

## **REMARKS**

The title of the application has been amended to more clearly describe the claimed invention. As such, the rejection to the specification has been obviated and should be withdrawn.

Claims 25-27 will be pending before the Examiner upon entry of the above amendments. Support for the amendments to the claims may be found throughout the instant specification. Specifically, example of support for the amendments to claim 25 can be found on page 19, line 12, to page 22, line 20. Example of support for the amendment to claim 27 can be found on page 15, line 10. Thus, the amendments to the claim are fully supported by the instant specification and no new matter has been introduced.

### **Rejections Under 35 U.S.C. § 101**

Claims 25-27 are rejected under 35 U.S.C. § 101 for directing to non-statutory subject matter. According to the Examiner, all steps of claim 25 can be taken place on a computer, which appear to lack any physical result performed outside of a computer. As such, the claims are directed to methods that merely manipulate numbers, abstract concepts, or ideas.

Applicant respectfully disagrees. Nowhere in claim 25 is there the mention of “computer.” Although certain steps of claim 25 may be performed by using a computer, it is clear that step (a) of claim 25 is not performed by a computer according to the teachings of the instant specification. The working examples of the instant specification (page 19-22) clearly illustrates that it requires physically scanning (or examining) of chromosomes of a population to obtain a plurality of single-nucleotide polymorphisms (“SNPs”) and a plurality of haplotypes (for example, see page 20, lines 1-6 of the instant specification). In other words, a computer cannot “provide” a plurality of SNPs and haplotypes, rather, the plurality of SNPs and haplotypes have to be transformed outside of the computer into computer data if a computer is used for the later steps. Moreover, claim 25 (and dependent claims), as amended, is directed to a method for determining whether a genetic region is associated with responsiveness to an agent. The resulting genetic associations are highly sought-after, and are useful in healthcare applications. The importance and commercial value of such method are well known to those skilled in the art. It is by no means a method “merely manipulates numbers, abstract concepts or ideas, or signals representing any of the forgoing.” (see Office Action, page 4, second paragraph from bottom).

In view of the foregoing, Applicant respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

**Rejections Under 35 U.S.C. § 112**

**A. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 25-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner states that steps in claim 25, other than step (a), do not necessarily keep the quantities of data separate between genetic regions, which makes it difficult for a skilled artisan to be able to make and use the invention that seeks to identify a genetic region associated with responsiveness to an agent. In other words, claim 25, according to the Examiner, does not address the scenario that more than one genetic region may form such an association, and if only one region is sampled as one of the options of step (a), a skilled artisan would automatically be identifying a genetic region associated with responsiveness to an agent.

Claim 25 has been amended to clarify what Applicant regards as the invention. As amended, claim 25 is directed to a method for determining whether a genetic region is associated with responsiveness to an agent. As such, only one genetic region is concerned at a time, and a skilled artisan can determine whether the genetic region in question is associated with responsiveness to an agent by following the steps of the claim. Therefore, claim 25 and its dependent claims are fully enabled, and the rejection under 35 U.S.C. § 112, first paragraph for enablement, should be withdrawn.

**B. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 25-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner rejected (1) claim 27 as vague and indefinite due to citing an abbreviation, "ANOVA;" (2) claim 25 for citing "associated with," which is vague and indefinite because it is unclear which parameters and to what degree these parameters must be met to be considered to be associated; (3) claim 25 for citing the limitation "said plurality" on line 5, because it is unclear if this phrase is referring to the plurality of single-nucleotide polymorphisms or the plurality of haplotypes in step (a); and (4)

claim 25 for reciting the phrase “at least weak,” which is unclear what parameters and to what degree these parameters must be met to be considered to be “at least weak.”

Claim 27 has been amended to recite the full name of the “ANOVA” test (see page 15, line 10) as suggested by the Examiner. See Office Action, page 7, 3<sup>rd</sup> paragraph from the bottom.

Applicant respectfully disagrees with the Examiner’s interpretation of “associated with” in claim 25. This is a term that is well understood in the art, and is explained in the instant specification. For example, the instant specification, on page 3, first paragraph, explains that a “p-value less than a predetermined limit establishes the association of said phenotype with occurrence of a particular set of allelic markers that occur at a plurality of genetic loci in a population of individuals.” Thus, for each determination, it would be apparent to a skilled artisan what “associated with” means by comparing the actual p-value to a predetermined p-value (which can be set by considering all known factors for that experiment, *e.g.*, sample size). As such, the phrase “associated with” is not vague nor indefinite.

Claim 25 has been amended to delete “said plurality” on line 5. Therefore, this rejection has been obviated.

Claim 25 has also been amended to delete the phrase “at least weak.” As amended, any SNPs in linkage disequilibrium is encompassed by the instant invention.

In view of the foregoing, Applicant respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

#### **Rejections Under 35 U.S.C. § 102**

Claims 25-27 are rejected under 35 U.S.C. § 102(e) (2) as being anticipated by Drysdale *et al.*, U.S. Patent No. 6,586,183 B2 (“Drysdale”). According to the Examiner, Drysdale discloses a method for identifying a genetic region associated with responsiveness to  $\beta$ -agonists, and anticipates the instant invention.

Applicant respectfully submits that the instant claimed invention includes at least one step (*e.g.*, step (d) of claim 25) that is not taught by Drysdale. Therefore, Drysdale does not anticipate the instant claimed invention.

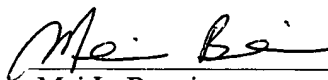
The instant claimed invention provides methods for determining whether a genetic region is associated with responsiveness to an agent. In particular, it includes a step (see step (d) of claim 25) that teaches how to choose a correlation test. This step is particular beneficial because it reduces sample size. Drysdale, on the other side, describes new SNPs in the  $\beta_2$ AR gene, and methods for predicting responsiveness to  $\beta$ -agonists. Drysdale does not teach how to choose a correlation test. On the contrary, Drysdale simply describes a laundry list of correlation tests that can be used in analyzing haplotypes (see columns 22-25 of Drysdale). Therefore, Drysdale does not teach step (d) of claim 25, and does not anticipate claim 25 and its dependent claims. As such, the rejection under 35 U.S.C. § 102(e) (2) should be withdrawn.

### CONCLUSION

Applicant respectfully requests that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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Enclosures